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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER VENCI, DAVID J	
			ART UNIT 1641	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/024,258

Applicant(s)

SCHELP ET AL.

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 20, 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 21, 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/01/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 20, 2007, has been entered.

Specification

The disclosure is objected to because of the following informalities:

In paragraph [0131]:

The abbreviated unit of measurement "pl" is not clear.

The first sentence has too many "and" words.

How "signal" is measured is not clear.

In paragraph [0133]:

Why "sample" is used in the standard assay is not clear.

The first sentence has too many "and" words.

How "signal" is measured is not clear.

Clarification is required.

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Drawings

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because Figure 2 is too small, data points are indistinguishable, and the x-axis labels do not align with anything.

Correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 19:

The phrase "wherein saturation of analyte A-binding sites of the binding partner R2 takes place at a higher analyte A concentration[...] than does saturation of analyte A-binding sites of the binding partner R3" is not clear. Whether/how merely determining ONE L1 signal in ONE incubation mixture establishes "saturation", analyte "concentration", or "higher" analyte concentration is not clear. The identity of one or more "samples" or "incubation mixtures" capable of catalyzing formation of "higher" analyte concentrations is not clear.

The phrase "wherein saturation of analyte A-binding sites of the binding partner R2 takes place at[...] b) at a later time in the incubation[...] than does saturation of analyte A-binding sites of the binding partner R3" is not clear. Whether/how merely measuring ONE L1 signal in ONE incubation mixture establishes "saturation" or saturation "at a later time" is not clear.

The standard or bases for ascertaining "a different time from an L2-dependent measurement signal" is indefinite because one or more temporal instances of "determining[...] an L2-dependent measurement signal" appears omitted from claims 1 and 19.

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The standard or bases for ascertaining "a different time from[...] an L1 plus L2-dependent measurement signal" is indefinite because one or more temporal instances of "determining[...] an L1 plus L2-dependent measurement signal" appears omitted from claims 1 and 19.

The standard or bases for ascertaining "a different measurement method than used to determine the L2-dependent measurement signal" is indefinite because one or more temporal instances of "determining[...] the L2-dependent measurement signal" appears omitted from claims 1 and 19.

The standard or bases for ascertaining "a different measurement method than used to determine the L1 plus L2-dependent measurement signal" is indefinite because one or more temporal instances of "determining[...] the L1 plus L2-dependent measurement signal" appears omitted from claims 1 and 19.

In claim 1, the purpose of "binding partner R3, which is associated with a label L2" in the overall method is not clear or appears extraneous.

In claims 4 and 20, the term "hook effect" is indefinite. The identity of one or more standards for ascertaining "hook effect", or lack thereof, or avoidance thereof, is not clear. Whether claim 4 requires knowledge or performance of some experimental error is not clear.

Claim 5, step (iii) is incomprehensible.

In claim 6, step (iii), the phrase "the L2-dependent measurement signal" lacks antecedent basis in claim 1. The identity of one or more temporal instances in claim 1 of "measuring" L2 is not clear.

In claim 19, the purposes of "binding partner R3", "a member X", "label L2", and "member Y" in the overall method are not clear or appears extraneous.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 16, 17 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Palomäki, 145 J. IMMUNOL. METHODS 55 (1991).

Palomäki describes a method comprising:

1. incubating a sample¹ with a binding partner² associated with a solid phase,³ a binding partner⁴ associated with a label⁵, and a binding partner⁶ associated with a label,⁷ wherein the binding partners have different affinity towards analyte;⁸ and
2. determining analyte label-dependent signals using different methods⁹ at different times.¹⁰

¹ See Abstract, second sentence, "specimen".

² See Abstract, second sentence, "Mab₁-HBsAg".

³ See Abstract, second sentence, "the solid phase is coated with Mab₁-HBsAg".

⁴ See Abstract, second sentence, "Pab-HBsAg".

⁵ See Abstract, second sentence, "peroxidase labelled Pab-HBsAg".

⁶ See Abstract, second sentence, "Mab₂-HBsAg".

⁷ See Abstract, second sentence, "peroxidase labelled[...] Mab₂-HBsAg".

⁸ See p. 61, left column, second full paragraph, *noting* a difference in the "optimal" assay concentration of Pab-HBsAg versus Mab₂-HBsAg. See also, Fig. 2, *noting* that said difference in "optimal" assay concentrations of Pab-HBsAg and Mab₂-HBsAg appear to give roughly the same signal response (*i.e.*, same slopes) suggesting an apparent difference in affinity towards analyte.

⁹ See p. 57, right column, fifth paragraph, "Colour development was allowed to proceed[...] and absorbances at 450 nm were then measured" (paraphrasing mine), *noting* Palomäki's use of eyeball and plate reader detectors.

¹⁰ See p. 58, right column, "Optimization".

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With respect to claims 5, 6 and 19, Palomäki describes a binding partner¹¹ associated with a member,¹² and a label¹³ associated with a member,¹⁴ which are added at a later time.

¹¹ See *supra*, note 6.

¹² See *supra*, note 7.

¹³ See p. 57, right column, fifth paragraph, "substrate solution[...] containing 0.1 mg/ml of 3,3',5,5'-tetramethylbenzidine".

¹⁴ See p. 57, right column, fifth paragraph, "substrate solution[...] containing[...] 0.005% (v/v) of H₂O₂".

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Claims 1-3, 7, 9-12, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein *et al.*, 121 J. AM. CHEM. SOC. 5336 (1999).

Klein *et al.* describe a method comprising:

1. incubating a sample¹⁵ with a binding partner associated with a solid phase,¹⁶ and binding partners¹⁷ associated with labels,¹⁸ wherein the binding partners have different affinity towards analyte;¹⁹ and
2. determining analyte label-dependent signals using different methods²⁰ at different times.²¹

¹⁵ See p. 5336, left column, first paragraph, "heterogeneous samples".

¹⁶ See Figure 1, "Binding ligand". (pick one)

¹⁷ See Figure 1, "Binding ligand". (pick two different ones)

¹⁸ See Figure 2, "¹H".

¹⁹ See Figure 1, "Increasing saturation".

²⁰ See Figure 2, *comparing* Fig. 2(a) versus 2(b).

²¹ See p. 5337, paragraph bridging left and right columns, last sentence.

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Claims 1-3, 7, 9-17, 19, 21 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Meinecke & Meyer, 44 J. MED. CHEM. 3059 (2001).²²

Meinecke & Meyer describe a method comprising:

1. incubating a sample²³ with a binding partner associated with a solid phase,²⁴ and binding partners²⁵ associated with labels,²⁶ wherein the binding partners have different affinity towards analyte;²⁷ and
2. determining analyte label-dependent signals using different methods²⁸ at different times.²⁹

With respect to claim 19, Meinecke & Meyer describe a binding partner³⁰ associated with a member,³¹ and a label³² associated with a member.³³

²² Applicants may overcome this rejection by filing an English translation of foreign priority document DE 100 64 827.4 in accordance with 37 CFR 1.55. See MPEP § 201.15.

²³ See paragraph bridging pp. 3059-3060, "substance mixture".

²⁴ See Figure 2, "RGD", "RGDS", "cyclo(RGDfV)". (pick one)

²⁵ See Figure 2, "RGD", "RGDS", "cyclo(RGDfV)". (pick two different ones)

²⁶ See Figure 1, "H".

²⁷ See Figures 2 and 6.

²⁸ See Figure 6, comparing Fig. 6(a) versus 6(b).

²⁹ See p. 3060, right column, *Materials and Methods*, last paragraph, "The spectra were subtracted internally via phase cycling after every scan"

³⁰ See *supra*, note 24.

³¹ See Figure 2, "RGD", "RGDS", "cyclo(RGDfV)". (pick one amino acid)

³² See Figure 2, "RGD", "RGDS", "cyclo(RGDfV)". (pick one proton)

³³ See Figure 1, " α_{11B} ", " β_3 ". (pick one)

Response to Arguments

Claim Rejections - 35 USC § 102

In prior Office Action, claims 1-4 and 7-9 were rejected under 35 U.S.C. 102(b) as being anticipated by Palomäki, 145 J. IMMUNOL. METHODS 55 (1991).

In response, Applicants argue that Palomäki does not teach "determining an L1-dependent measurement signal **at a different** time from an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal" (see Applicants' reply, paragraph bridging pp. 3-4) (emphasis in original).

Applicants' argument is not persuasive. The standard or bases for ascertaining "a different time from an L2-dependent measurement signal" is indefinite because one or more temporal instances of "determining[...] an L2-dependent measurement signal" appears omitted from claims 1 and 19. Similarly, the standard or bases for ascertaining "a different time from[...] an L1 plus L2-dependent measurement signal" is indefinite because one or more temporal instances of "determining[...] an L1 plus L2-dependent measurement signal" appears omitted from claims 1 and 19.

What is definite is that Palomäki describes the only measurement step Applicants definitively claim—"determining an L1-dependent measurement signal".

Claim Rejections - 35 USC § 103

In prior Office Action, claims 5, 6 and 19-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Palomäki, 145 J. IMMUNOL. METHODS 55 (1991), in view of Marquardt *et al.* (US 6,610,494). Claims 10-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Palomäki, 145 J. IMMUNOL. METHODS 55 (1991), in view of Cragle *et al.* (US 4,590,169). And, claims 16 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Palomäki, 145 J. IMMUNOL. METHODS 55 (1991), in view of Pitner *et al.* (US 5,641,629). Notwithstanding Applicants' argumentation, these rejections are withdrawn.

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Conclusion

No claims are allowable at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Assistant Examiner
Art Unit 1641

djv


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11/13/07